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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,525	02/27/2004	Richard James Cawthray	02911.012130.	7746
5514 7590 06/08/2010 FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
06/08/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,525

Applicant(s)

CAWTHRAY ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 11, 14, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 11, 14, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed May 14, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objection

Claim 14 is objected to because of the following informalities: the term "wherein" should be inserted after "Claim 2" and before "said". Appropriate correction is required.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1, 2, 4, 11, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Kelly (US 4,817,819) in further view of Palo Alto Medical Foundation (January 2002).

Daifotis et al. has been discussed in the previous Office Action mailed March 18, 2009. The reference discloses using risedronate in a regimen along with calcium. The reference differs from the instant claims insofar as it does not disclose the blister pack comprises 4 unit dosages of the bisphosphonate and 24 unit dosages of calcium arranged in the order in accordance with Figure 3 or Figure 5.

Kelly discloses a container for tablets and has also been discussed in the Office Action mailed March 18, 2009. The reference differs from the instant claims insofar as it does not disclose the tablets are bisphosphonate and calcium.

It would have been obvious to one of ordinary skill in the art to have used a blister pack with four rows with seven spaces each to use in the kits of Daifotis et al. motivated by the desire to use a blister pack and container that is labeled with the day therapy begins and is suitable for use for storing pills that are to be taken once a day.

In regards to claims 11 and 14, The Supreme Court has held that while the "teaching, suggestion, motivation" approach is a valid form of analysis under *Graham v. Deere*, it is not the only one. See *KSR v. Teleflex*, 82 USPQ2d 1385 (U.S. 2007) at page 1397 where Justice Kennedy, speaking for a unanimous court, states:

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try."... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

It would have been obvious to one of ordinary skill in the art to have arranged the pharmaceuticals and nutrients as seen in Figure 3 and Figure 5 motivated by the desire to arrange the components in a pattern that promotes dosing in a particular order. Since

there are only a finite number of ways to arrange the pharmaceuticals and nutrients in the blister packs such as horizontally, vertically and in a circular pattern, it would have been obvious to arrange the components as seen in Figure 3 and Figure 5¹.

The combination of Daifotis et al. and Kelly differ from the instant claims insofar as it does not disclose the doses of calcium administered in the kits.

Palo Alto Medical Foundation discloses the amounts of calcium and vitamin D recommended for body function including bone growth and maintenance. The amounts range from 210 mg for a baby to 1500 mg for an adult (see Table, 1000 mg to 15000 mg for an adult). Vitamin D is critical to the absorption of calcium from the gastrointestinal tract and in bone formation. The amount of vitamin D ranges from 200 IU to 600 IU. Supplements that contain 400 IU of vitamin D are common doses (see page 1 of 4, last paragraph). The reference differs from the instant claims insofar as it does not disclose a kit comprising 4 unit doses of bisphosphonate and 24 unit doses of calcium; or 4 unit doses of bisphosphonate and 24 unit doses of a mixture of calcium and vitamin D.

It would have been obvious to one of ordinary skill in the art to have supplied the calcium of the combined teachings of Daifotis et al. and Allendorf et al. at a dosage of between 1000 mg and 1500 mg per day motivated by the desire to use an amount suggested for good bone health as disclosed by Palo Alto Medical Foundation.

¹ In any case, a claimed device is not patentably distinct from the prior art if the claimed device would not perform differently than the prior art device. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

It would have been obvious to have administered a combination of calcium and vitamin D in the kits of the combined teachings of Daifotis et al. and Allendorf et al. motivated by the desire to ensure calcium absorption as disclosed by Palo Alto Medical Foundation.

2) Claims 1, 2, 4, 11, 14, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daifotis et al. (US 5,994,329) in view of Allendorf et al. (US 5,265,728) in further view of Palo Alto Medical Foundation (January 2002).

Daifotis et al. has been discussed in the previous Office Action mailed March 18, 2009. The reference discloses using risedronate in a regimen along with calcium. The reference differs from the instant claims insofar as it does not disclose the blister pack comprises 4 unit dosages of the bisphosphonate and 24 unit dosages of calcium arranged in the order in accordance with Figure 3 or Figure 5.

Allendorf et al. disclose a blister pack comprising enough spaces for a twenty-one-day or twenty-two-day cycle and has also been discussed in the Office Action mailed March 18, 2009. The reference differs from the instant claims insofar as it does not disclose the tablets are bisphosphonate and calcium.

It would have been obvious to one of ordinary skill in the art to have used a blister pack with four rows with seven spaces each in the kits of Daifotis et al. motivated by the desire to use a blister pack and container that is labeled with which pill to start therapy with and has an arrow to direct a patient to the next pill to ensure the medication is taken in the right order.

In regards to claims 11 and 14, The Supreme Court has held that while the "teaching, suggestion, motivation" approach is a valid form of analysis under *Graham v. Deere*, it is not the only one. See *KSR v. Teleflex*, 82 USPQ2d 1385 (U.S. 2007) at page 1397 where Justice Kennedy, speaking for a unanimous court, states:

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." ... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

It would have been obvious to one of ordinary skill in the art to have arranged the pharmaceuticals and nutrients as seen in Figure 3 and Figure 5 motivated by the desire to arrange the components in a pattern that promotes dosing in a particular order. Since there are only a finite number of ways to arrange the pharmaceuticals and nutrients in the blister packs such as horizontally, vertically and in a circular pattern, it would have been obvious to arrange the components as seen in Figure 3 and Figure 5 (see footnote 1).

The combination of Daifotis et al. and Allendorf et al. differ from the instant claims insofar as it does not disclose the doses of calcium administered in the kits.

Palo Alto Medical Foundation discloses the amounts of calcium and vitamin D recommended for body function including bone growth and maintenance and is discussed above. The reference differs from the instant claims insofar as it does not disclose a kit comprising 4 unit doses of bisphosphonate and 24 unit doses of calcium; or 4 unit doses of bisphosphonate and 24 unit doses of a mixture of calcium and vitamin D.

It would have been obvious to one of ordinary skill in the art to have supplied the calcium of the combined teachings of Daifotis et al. and Allendorf et al. at a dosage of between 400 mg and 1500 mg per day motivated by the desire to use an amount suggested for good bone health as disclosed by Palo Alto Medical Foundation.

It would have been obvious to have administered a combination of calcium and vitamin D in the kits of the combined teachings of Daifotis et al. and Allendorf et al. motivated by the desire to ensure calcium absorption as disclosed by Palo Alto Medical Foundation.

Claims 1, 2, 4, 11, 14, 25 and 26 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612